



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/403,429 10/20/99 SHIMIZU

T 2535USQP

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TAKEDA PHARMACEUTICALS AMERICA, INC
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EXAMINER

TRAN, S

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

4
06/13/00

**Please find below and/or attached an Office communication concerning this application r
proceeding.**

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/403,429

Applicant(s)

Shimizu et al.

Examiner

Susan Tran

Group Art Unit

1615



- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-19 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-19 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☒ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Receipt is acknowledged of applicants' Preliminary Amendment A filed 10/20/99.

Claim Objections

1. Claims 3, and 13-17 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-7, 9, and 13-19 rejected under 35 U.S.C. 102(e) as being anticipated by Ohno et al. USPN 5,958,453 ('453).

Ohno teaches a pharmaceutical composition in solid, powder or granular form in a tablet comprising mannitol or erythritol (column 2, lines 13-67), and voglibose as active ingredient (column 4, lines 13-22). The composition further comprising disintegrant agent, i.e., low substituted hydroxypropyl cellulose at about 1-15 parts by weight based on 100 parts by weight of

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the solid pharmaceutical composition (column 5, lines 14-59). The tablet can be completely dissolve in about 0.1-1.0 minute (column 6, lines 63-68).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al. ('453), in view of Shashoua et al. USPN 5,795,909.

Ohno is relied upon for the reasons stated above. The reference differs from applicants claimed invention by not specifically teaching all the claimed active ingredients.

Shashoua teaches a pharmaceutical composition in a tablet form comprising active ingredients, i.e., pioglitazone (column 27, lines 12-25), lansoprazole (column 35, lines 4-10), candesartan, and manidipine (column 41, lines 62 through column 46, lines 1-16). Thus it would have been prima facie obvious to one of the ordinary skill in the art at the time this invention was made to prepare the Ohno et al. pharmaceutical composition with the active ingredients in view of the teaching of Shashoua et al. to obtain the claimed invention because the references teach the advantageous accrue in the use of the active ingredients and disintegrant agent, namely the quick dissolve tablet.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600